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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,766	02/18/2000	Shlomo Ben-Haim	BIO-95	8645

7590 10/25/2002

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EXAMINER
OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/506,766	Applicant(s) BEN-HAIM ET AL.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment filed 9/3/02

1. Claims 1-51 are pending in this Application.

The Applicant filed a Request for Continued Examination and amended independent claims 1, 12, 16, 35, 42 and 47. A grounds of rejection for claims 1-51 is established below in paragraphs 2-4.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/3/02 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As related to claims 1, 12, 42 and 47, the specification does not disclose how the location of the minimum volume of the chamber of the heart is determined using the location of the non-contact electrodes and how it defines a cloud of space.

As related to claims 16 and 35, the specification does not disclose how the minimum volume of the heart chamber is determined using the location of the non-contact electrodes and how it defines a cloud of space.

Although the specification states on page 17 that this can be accomplished, it is unclear how it is accomplished, what equations are used and what minimum volume is actually being defined.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As related to claims 1, 12, 42 and 47, it is unclear if the minimum volume of the chamber of the heart and defined cloud of space is the volumetric sphere of sensing or the minimum volume the heart achieves, etc..

As related to claims 16 and 35, it is unclear if the minimum volume of the heart chamber is the volumetric sphere of sensing or the minimum volume the heart achieves, etc..

For claims 1, 12, 42 and 47, the claims are vague since it is unclear if the sensor or another element, such as a processor, is actually "determining" the location of said non-contact

electrodes defining a cloud of space and if this is a positive recitation of that determination and the "defining " of a cloud of space.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. Claims 1-3, 7, 9, 10, 12, 13, 15-18, 22, 24, 25, 32-37, 39-45 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) in view of Goldreyer (US 5385146).

Ben Haim et al. disclose a method and apparatus to treat arrhythmias with ablation using one or more catheters (abstract). The tip of the catheter contains an electrode which can function at a site in the heart to sense electrical cardiac activity, to act as an antenna to deliver radio-frequency energy to perform ablation of tissue, or to deliver stimuli for pacing the heart (c 11, ll 28-35). The electromagnetic location system in the tip of the catheter can contain between one and ten antennas to define the location of the tip area of the catheter (c 11, ll 49-59). In figure 16, a tip electrode (105) and additional electrodes (106) are disclosed. The receiving antennas, located near the distal tip of the catheter (c 12, ll 41-47), provide location information for the local activation data received from the tip electrode (105) and additional electrodes (106) (c 7, ll 15-25; c 10, ll 33-45; claims 30 and 31).

Ben-Haim et al. disclose the claimed invention except for:

- the electrodes being non-contact electrodes linearly arranged along a longitudinal axis of the catheter body, and

- the location of the non-contact electrode determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart

(claims 1 and 2), determining a location of said contact electrode and a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contract electrode defines a cloud of space and determining a minimum volume of said heart chamber using the location of said non-contact electrodes (claims 16 and 35), at least one location sensor for determining a location of said contact electrode and location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 42) and at least one location sensor for determining a location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 48).

Goldreyer discloses a catheter to sense extremely localized intracardiac electrical pattterns.

As related to the non-contact electrodes arranged linearly, figures 1 and 2 disclose a catheter (10/32) including a stimulating tip (14) and non-contact electrodes (34-46) shown to be 14 electrodes, read to be about 16 electrodes (c 5, ll 6-12). Goldreyer teaches an embodiment where the electrodes are non-contact (c 2, ll 10-11) and are linearly arranged along a longitudinal axis of the catheter body to enable simultaneous sensing and ablation and/or pacing activity (c 1, ll 55-59). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, and provide electrodes being non-contact electrode linearly arranged along a longitudinal axis of the catheter body as taught by Goldreyer to enable

simultaneous sensing and ablation and/or pacing activity so accurate and discrete mapping of the electrophysiologic activation within the heart is achieved (c 1, l 63 – c 2, l 4).

As related to the representation of the minimum volume of the heart chamber, Goldreyer teaches heart chamber mapping by sensing local cardiac signals in a minimal area of the heart chamber and repeating this process at predetermined positions within the chamber until accurate and discrete mapping of electrophysiologic activation within the heart is achieved (c 1, l 55 – c 2, l 11), hence the definition of the minimum volume of the heart chamber is accomplished by defining the location of the activation data within the heart chamber by a location sensor as disclosed by Ben-Haim et al. and by the predetermined position of the non-contact electrodes on the catheter as taught by Goldreyer (c 2, ll 38-42 and 51-56 and c 3, ll 53-60). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, and provide:

the location of the non-contact electrode determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claims 1 and 2), determining a location of said contact electrode and a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contract electrode defines a cloud of space and determining a minimum volume of said heart chamber using the location of said non-contact electrodes (claims 16 and 35), at least one location sensor for determining a location of said contact electrode and location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 42) and at

least one location sensor for determining a location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 48)

as taught by Goldreyer to enable accurate and discrete mapping of electrophysiologic activation within the heart so optimal clinical treatment is provided to the patient (c 1, ll 7-11).

6. Claims 4-6, 14, 19-21, 26-31, 38, 46 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al. (US5718241) and Goldreyer (US 5385146) in view of Martinelli (US 6104944). As discussed in paragraph 5 of this action, modified Ben-Haim et al. disclose the claimed invention except for providing six degrees of location information using locations sensors in a proximate and a distal position relative to the electrode array.

Martinelli discloses a system and method for navigating a multiple electrode catheter and teaches that it is known to use two or more navigated electrode elements (N1-Nn), read as location sensors, between multiple virtually navigable electrode elements (E1-En), read as an array of non-contact electrodes (column 4, line 66 – column 5, line 8 and column 5, lines 24-33) to define the position of electrodes in a domain such as a chamber of the heart (column 4, lines 63-66). Martinelli teaches the use of electromagnetic field sensors as the navigated electrode elements to provide navigational location information (column 6, lines 18-32). These navigated electrode elements provide orientation data and position coordinate data, read as the six degrees of location information (column 6, lines 54-64 and column 8, lines 29-65), to establish the location of the virtually navigated electrodes and enable accurate mapping of the heart.

Therefore it would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify the modified method and apparatus to treat arrhythmias with ablation as taught by modified Ben-Haim, providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array as taught by Martinelli to enable accurate mapping of the heart so arrhythmia producing cardiac tissue is identified and can be ablated.

7. Claims 8, 11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (US 5718241) and Goldreyer (US 5385146) in view of Swanson et al. (US 6171306). As discussed in paragraph 5 of this action, modified Ben-Haim discloses the claimed invention except for the distal tip contact electrode being a bipolar electrode. Swanson et al. disclose an ablation catheter and teach that it is known to use a bipolar distal tip electrode to ablate the cardiac tissue (figure 5, and column 7, lines 11-14). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by modified Ben-Haim, with a bipolar distal tip electrode as taught by Swanson et al. to utilize the electrodes in the device, the tip and the array electrodes, to ablate the tissue, eliminating the need for the addition of an external indifferent electrode (column 7, lines 17-20). Utilizing a bipolar configuration also provides a more targeted ablating stimulus enabling more precise ablation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
10/23/02

GEORGE R. EVANISKO
PRIMARY EXAMINER
10/24/2